



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark R. Kreitz, Yong S. Jong, Edith Mathiowitz, David J. Enscoe and
Michael J. Bassett

Serial No.: 10/696,829 Art Unit: Not Yet Assigned

Filed: October 30, 2003 Examiner: Not Yet Assigned

For: *NANOPARTICULATE BIOACTIVE AGENTS*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including three (3) pages of Form PTO-1449 and copies of thirty-three (33) documents cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

| <u>Number</u> | <u>Issue Date</u> | <u>Patentee</u> | <u>Class/Subclass</u> |
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| 4,757,128 | 07-12-1988 | Domb, et al. | 528/271 |
| 4,997,904 | 03-05-1991 | Domb | 528/206 |
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| <u>Number</u> | <u>Publication Date</u> | <u>Patentee</u> | <u>Country</u> |
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| WO 93/21906 | 11-11-1993 | Brown University Research Foundation | PCT |
| WO 97/15269 | 05-01-1997 | Baker Norton Pharmaceuticals, Inc. | PCT |
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Publications

BECK, et al., "A new long-acting injectable microcapsule system for the administration of progesterone," *Fertil. & Steril.*, 31(5): 545-55 (1979).

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BODMEIER & PAERATAKUL, "Spherical agglomerates of water-insoluble drugs," *J. Pharm. Sci.* 78(11): 964-967 (1989).

GENTA, et al., "Improvement of dexamethasone dissolution rate from spray-dried chitosan micropsheres," *S.T.P. Pharma Sciences* 5(3): 202-207 (1995).

IMAI, et al., "Rapidly absorbed solid oral formulations of ibuprofen using water-soluble gelatin," *J. Pharm. Pharmacol.* 42: 615-619 (1990).

MATHIOWITZ, et al., "Novel microcapsules for delivery systems," *Reactive Polymers*, 6:275-83 (1987).

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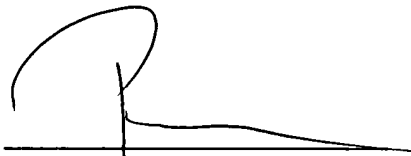
MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery systems," *Scanning Microscopy* 4: 329-340 (1990).

WAUGH, et al., "Stability, compatibility, and plasticizer extraction of taxol (NSC-125973) injection diluted in infusion solutions and stored in various containers," *Am. J. Hosp. Pharm.* 48: 1520-1524 (1991).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'Pabst', written over a horizontal line.

Patrea L. Pabst
Reg. No. 31,284

Dated: March 3, 2004

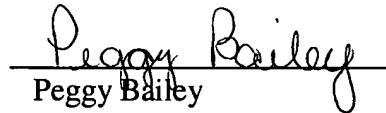
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Filed: October 30, 2003
INFORMATION DISCLOSURE STATEMENT

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Peggy Bailey

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

| | |
|------------------------|------------------|
| Application Number | 10/696,829 |
| Filing Date | October 30, 2003 |
| First Named Inventor | Mark R. Kreitz |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket Number | SPS 102/105 |

Sheet 1 of 3

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | US Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|--------------------|-----------------------------------|---|-----------------------------------|---|
| | | Number | Kind Code ² (if known) | | | |
| | | 4,757,128 | | Domb, et al. | 07-12-1988 | |
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FOREIGN PATENT DOCUMENTS

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|--------------------|-----------------------|-------------------------|---------------------|-----------------------------------|---|--|---|----------------|
| | | Office. ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| | | PCT | WO 93/21906 | | Brown University Research Foundation | 11-11-1993 | | |
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| | | Application Number | 10/696,829 | | |
| | | Filing Date | October 30, 2003 | | |
| | | First Named Inventor | Mark R. Kreitz | | |
| | | Group Art Unit | | | |
| | | Examiner Name | | | |
| Sheet | 3 | of | 3 | Attorney Docket Number | SPS 102/105 |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS | | | |
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| Examiner's Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T ² |
| | | BECK, et al., "A new long-acting injectable microcapsule system for the administration of progesterone," <i>Fertil. & Steril.</i> , 31(5): 545-55 (1979). | |
| | | BENITA, et al., "Characterization of Drug-Loaded Poly(D,Lactide) Microspheres," <i>J. Pharm. Sci.</i> , 73(12): 1721-24 (1984). | |
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| | | GENTA, et al., "Improvement of dexamethasone dissolution rate from spray-dried chitosan micropsheres," <i>S.T.P. Pharma Sciences</i> 5(3): 202-207 (1995). | |
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| | | MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery systems," <i>Scanning Microscopy</i> 4: 329-340 (1990). | |
| | | WAUGH, et al., "Stability, compatibility, and plasticizer extraction of taxol (NSC-125973) injection diluted in infusion solutions and stored in various containers," <i>Am. J. Hosp. Pharm.</i> 48: 1520-1524 (1991). | |
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